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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,153	03/21/2001	Steven M. Ruben	PZ023P1C1	2908

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EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,153	RUBEN ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,17,19,22-25,30-39 and 44-58* is/are pending in the application.

4a) Of the above claim(s) *1,11,17,19 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,30-39, and 44-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. The amendment filed January 06, 2004 have been entered. The status of the claims is as follow: Claims 2-10, 12-16, 18, 20-21, 26-29, and 40-43 have been canceled. Claims 1, 11, 17, 19, 22-25, 30-39, 44-58 are pending. Claims 1, 11, 17, 19, and 22-24 are withdrawn from examination. Claims 25, 30-39, and 44-58 are under examination.

Claim Objections

2. The previous claims objections are withdrawn in view of Applicant's amendment, January 06, 2004.

Specification

3. The specification is objected to because there is multiple "Table 5". Applicant is suggested to amend subsequent "Table 5" to "Table 5 continued" to obviate this objection.

Claim Rejections - 35 USC § 101

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 25, 30-39, and 44-58 remain rejected under 35 U.S.C. and 35 U.S.C. 112, first paragraph.

A) Applicant argues that there is no requirement under 35 U.S.C. § 101 that an inventor teach the scientific principle of the invention nor are Applicants aware of nay requirement that an applicant describe the "specific activity" of a polypeptide before said polypeptide is deemed to satisfy the utility requirement under 35 U.S.C. § 101.

Applicant asserts that Applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112, and that additional statements of utility, even if not "credible" do not render the claimed invention lacking in utility. Applicant points to Raytheon v. Roper. Applicant further states that there is nothing improper about reciting multiple utilities for an invention.

Applicant's arguments can be fully considered, but are found unpersuasive. As applicant points out in the cited case law stating that utility is shown when the invention meets at least one stated objection, the instant invention has not met at least one objection. There is no specific or substantial use for the antibody claimed because the specification has not described a specific or substantial use for the polypeptide claimed. While applicant is correct that there is nothing improper about reciting multiple utilities for a polypeptide, the instant disclosure merely speculates potential uses for the polypeptide and the antibody that binds to the polypeptide. There is no credible evidence or data in the specification indicating that the polypeptide and the antibody that binds to it would be useful in any of the methodologies recited. For example, on page 56, lines 6-16, the specification asserts that the polypeptides of the invention are useful for the differential identification of tissues and cell types in a sample. The specification does not provide a clear explanation for how this is accomplished by the polypeptide or why one would be interested in identifying tissues and cell types with this polypeptide. There is no correlation between identifying tissues and cell types and the significance of the polypeptide. The disclosure also states that the polypeptide is used to diagnosis diseases and conditions, but again, there is no teaching provided for how

this is accomplished or what the significance of detecting diseases or conditions with this polypeptide is. There is no specific cell, tissue, disease or condition specifically identified in the disclosure that is directly associated with the polypeptide or the antibody that binds to it. Therefore, applicant has not provided at least one objection required to satisfy 35 U.S.C. § 101.

B) Applicant submits that the use of the polypeptide of this invention for the diagnosis of skeletal disorders, such as osteoclastoma is a credible assertion of and specific utility. Applicant continues to submit that the instant specification discloses a biological activity, and reasonably correlates the activity to a disease or condition. Applicant points to a passage in the specification that identifies diagnosing skeletal disorders, such as osteoclastoma and asserts that this teaching satisfies the specificity and substantial requirements.

Applicant's assertion has been fully considered, but is found unpersuasive. Although the specification states that the gene is primarily expressed in osteoclastoma and brain tissues, there is no evidence to suggest that identifying the protein with the gene would be indicative or specific for identifying osteoclastoma development because the gene is also expressed in other tissues, i.e., brain, neural and skeletal tissues. There is no evidence that would suggest that the instant polypeptide or the antibody claimed would allow the skilled artisan be able to differentiate between the development of osteoclastoma and the presence of other tissues in a biological sample. Therefore, it is maintained that, while identifying osteoclastoma is a public benefit, the instant

disclosure does not provide evidence that the polypeptide or the instant antibody is has a substantial utility for the asserted purpose.

C) Applicant argues that the instant invention can be utilized in the diagnosis of osteoclastoma, regardless of its expression in other tissues through biopsy of the bone tumor. Applicant asserts that the expression of the molecular marker, i.e., the instant polypeptide and the antibody that binds to the polypeptide, has specific, credible and substantial utility to detect osteoclastoma.

Applicant's arguments have been fully considered, but are found unpersuasive. Due to the teaching in the specification that expression of the gene is present in other tissues, the assertion that the instant polypeptide and antibody specifically detects osteoclastoma has not been demonstrated. In the passage recited by applicant on page 18 of the response, the higher or lower levels of gene expression detected in neural tissues, skeletal tissues, cancerous tissues, wounded tissues, body fluids and any other tissue or cell from an individual having such a disorder is relative to the standard expression level from a normal individual. However, there is no teaching provided in the specification what a normal level of expression is or what would be a higher or lower level of expression in relation to it. There is no evidence that the instant antibody would be able to differentiate between product expression levels in a normal individual or one with any type disorder. Therefore, it is maintained that use of the instant antibody does not meet the criteria required by 35 U.S.C. § 101.

Applicant also states that a rejection under 35 U.S.C. § 112, first paragraph should not be made if a rejection under 35 U.S.C. § 101 is improper. Applicant is

correct. In the instant case, the grounds of rejection under 35 U.S.C. § 101 is proper and is being maintained. Therefore, the rejection under 35 U.S.C. § 112, first paragraph is also proper.

Claim Rejections - 35 USC § 112

5. Applicant argues that the specification provides ample teaching for how to make and use the instant antibodies and points to specific passages in the disclosure.

In response, while the specification reiterates general practices well-known in the art regarding how to make and use antibodies, examples and teachings in the disclosure are only prophetic and do not exemplify a specific, substantial or credible use. It is maintained that there is no teaching in the disclosure provided for how to make or use the instant antibody in a manner that would enable the skilled artisan to practice the invention without undue experimentation.

Claim Rejections - 35 USC § 102

6. The written description under 35 U.S.C. § 112, first paragraph, deposit of biological material, is withdrawn in view of Applicant's response.

7. Claims 25, 30-39, and 44-58 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (WO94/04563, "Yamada"). The rejection of the claims are based on the language used in U.S. Patent NO. 5,733,549, which is a U.S.C § 371 of PCT/JP93/01142, which is WO94/04563.

Applicant argues that anticipation can only be established by a single prior art reference that discloses each and every element of the claimed invention. Applicant

further argues that the Examiner improperly distilled Applicant's claimed invention down to an antibody that recognizes a 7 amino acid region and has made the assumption that this region constitutes an antigenic epitope.

Applicant's arguments and traversal has been fully considered. However, it is not found persuasive. Applicant is correct to point out that anticipation can only be established by a single prior art reference that discloses each and every element of the claimed invention. However, the rejection is maintained because there is no teaching in the disclosure for the antigenic epitopes on a polypeptide having SEQ ID NO: 125. Thus, it is expected that any antibody that binds to at least 7 amino acids, the minimum number of amino acids required for an antigenic epitope—as defined by line 6-10 of the specification, that are present in SEQ ID NO: 125 is expected to bind to SEQ ID NO: 125. Further, Applicant has not provided any evidence that the antibody taught by Yamada et al. is not the antibody that is instantly claimed.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le
Emily Le

James C. Housel 3/8/04
JAMES HOUSEL
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